Additional Information – Supplementary material

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Supplementary Table S1. Pharmaceutical revenue in Brazil in 2019, by regulatory category

Regulatory category	Revenue (BRL)	Revenue ($ PPP)[1]	%	Sales Volume (Units)	%
New drugs[2]	30,532,655,438.53	13,385,644,646.44	35.5	889,658,614.00	16.9
Biologics	21,840,136,916.23	9,574,807,942.23	25.4	163,670,438.00	3.1
Branded generics ("*Similares"*)	17,238,652,065.17	7,557,497,617.35	20.1	1,869,723,205.00	35.5
Generics	11,745,994,188.09	5,149,493,287.19	13.7	1,848,780,052.00	35.1
Others	4,573,964,917.34	2,005,245,470.12	5.3	489,431,876.00	9.3
Total	**85,931,403,525.36**	**37,672,688,963.33**	**100.0**	**5,261,264,185.00**	**100.0**

[1]PPP: Purchase Parity Power (World Bank, 2019): 2.281; [2]New drugs: New Medicine: synthetic and semi-synthetic active ingredients, associated or not.
Source: Brasil. Câmara de Regulação do Mercado de Medicamentos. Secretaria Executiva. Anuário Estatístico do Mercado Farmacêutico 2019/2020. Brasília, DF, 2021. Available at: https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/informes/anuario-estatistico-2019-versao-final.pdf

Supplementary Table S2. Regulation, pricing, and reimbursement: relevant websites

Theme	Content[1]	Link to Website
Legislation (Website of the Brazilian Presidency)	Legislation of the federal and state governments, judiciary, international agreements, etc.	http://www4.planalto.gov.br/legislacao/
Portal Fala.br (Website of the Brazilian Government)	Integrated portal for the ombudsman, information requests on the grounds of Law of Information Access (LAI), complaints, reporting wrongdoing, etc.	https://falabr.cgu.gov.br/publico/Manifestacao/SelecionarTipoManifestacao.aspx
Brazilian Clinical Trial Registry (ReBEC)	Public Brazilian clinical trial registry (Portuguese/English)	https://ensaiosclinicos.gov.br/
Information on Medicines	Anvisa's hub for information related to medicines	https://www.gov.br/anvisa/pt-br/assuntos/medicamentos
Medicines: concepts and definitions	Glossary with officially adopted definitions	https://www.gov.br/anvisa/pt-br/acessoainformacao/perguntasfrequentes/medicamentos/conceitos-e-definicoes/conceitos-e-definicoes
Regulatory thematic library: medicines	Anvisa's updated regulations related to medicines, organised by themes in medicines' life cycle	https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/legislacao/bibliotecas-tematicas/arquivos/medicamentos
Regulatory thematic library: crosscutting areas	Anvisa's updated regulations organized by regulatory processes	https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/legislacao/bibliotecas-tematicas/arquivos/biblioteca-de-temas-transversais
Anvisa's consultation page	Consultation on information systems related to regulatory activities such as marketing authorization status, public medicine assessment reports, leaflets, etc.	https://consultas.anvisa.gov.br/#/
Post-marketing and enforcement information	Information, access to information systems, notifications, etc.	https://www.gov.br/anvisa/pt-br/assuntos/fiscalizacao-e-monitoram§ento
Pharmacovigilance	System for reporting suspected adverse events to drugs and vaccines on VigiMed (Notification system for unexpected reactions to drugs and vaccines)	https://primaryreporting.who-umc.org/BR
Drug Market Regulation Chamber (CMED)	CMED information, legislation, publications, access to price lists, etc.	https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed
CMED: Lists of medicine prices	Updated lists with maximum approved prices (ex-factory, maximum consumer's prices, maximum government procurement prices with different state taxes/duties), including access to previous lists	https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/precos
CMED: Legislation	Medicine price regulation laws, decrees and specific CMED	https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/le

Theme	Content[1]	Link to Website
	regulations	gislacao
Information on Medicines Market Monitoring System (Sammed)	Manual for applicants on how to use Sammed	https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/informes/manual-do-sistema-sammed-web-versao-1-1.pdf
National Committee for Health Technology Incorporation at SUS (Conitec),	General information about the Committee, access to ongoing assessments and approved medicines and other technologies, open public consultations, technology horizon scan and mechanisms for social participation	http://conitec.gov.br/
National Price Registry (BPS)	General information with objectives, manuals, supporting legislation about the national price registry	https://www.gov.br/saude/pt-br/acesso-a-informacao/banco-de-precos
Login page for the National Price Registry	Access to the national price registry (includes the Integrated System for the Administration of General Services - SIAG) (Portuguese, English and Spanish)	http://bps.saude.gov.br/login.jsf
National Regulatory Agency for Private Health Insurance and Plans (ANS) procedure's list (coverage)	Information about the list, access to the latest list and procedure for updating	https://www.gov.br/ans/pt-br/assuntos/consumidor/o-que-o-seu-plano-de-saude-deve-cobrir-1/o-que-e-o-rol-de-procedimentos-e-evento-em-saude

[1]The content is in Portuguese, when not indicated otherwise.

Supplementary Figure S1. Judicialisation as a means of bypassing marketing authorization, pricing, and reimbursement

Based on the constitutional right to health, patients in Brazil resort to the courts to have access to services, medicines and other technologies. This phenomenon is known as "judicialisation" and occurs sometimes even before its marketing authorisation by Anvisa and the price approval by CMED, usually at higher prices than the authorised and also before its assessment by CONITEC.[1–4] Judicialisation creates a dilemma as it puts the right of a patient to a given treatment, no matter the costs or circumstances of care, against the right of all members of society to access to technologies proven to be safe, effective, of good quality and more cost-effective in a budget-constrained health system.[5–7]

"Judicialisation" became an "epidemic" as the number of lawsuits related to access to medicines and other health products increased from 200,090 in 2015 to 544,378 in 2018.[8] In 2019, there were 60,000 ongoing court cases related to rare diseases in Brazil, generating unprogrammed expenses of over R$ 500 million (US $ 92.7 million) per year.[9] In 2021, there were around 42,000 court cases for the provision of unapproved high-priced drugs. The situation is unsustainable, as it unhinges the legally established public policies and regulatory systems, budget planning and resource allocation.[5,6]

Access to medicines and other technologies is intended to leave no one behind through the right to health. Nevertheless, judicialisation can contribute to increasing inequities as patients with access to the judiciary system will likely be successful with their claims. While patients without the same access can be left behind.[7] In addition, judicialisation places the burden on the payer and displacing unplanned resources, has an opportunity cost, as it prevents the system to provide more cost-effective interventions for everyone, including the poor who depend on the national health system (SUS).[6,7,10]

The National Justice Council (CNJ), the Brazilian high court, after public consultation and intense debates reached a decision that the SUS is not obliged to provide medicines without proven efficacy, safety and quality and not approved through marketing authorisation by Anvisa *[tese de repercussão geral].* The court decided that exceptions could be accepted, but details are yet to be decided by the CNJ.[11–14]

In addition, there are several resources available to support the judges' decision-making based on sound evidence, such as the repository of technical documents (e-NATJUS) and a network of Technical Support Centres of the Judiciary Power – NATJUS.[15] However, it can be argued that judges are not trained to assess epidemiologic and other evidence on pharmaceuticals for such decisions.

Supplementary Figure S2. Key institutional arrangements related to pharmaceutical pricing and reimbursement policies in Brazil

The Brazilian Health Regulatory Agency (Anvisa) established by Law 9,782/1999 is one of eleven federal regulatory agencies in Brazil.[16] Anvisa, together with the Brazilian Health Regulatory System (SNVS), regarded as a Unified Health System (SUS) sub-system, regulates all health-related products and services, including medicines and other health technologies in different steps of their life cycle and traveller's health.[16,17]

The economic regulation in Brazil was set up in 2001, with the Drug Regulation Chamber (CAMED) as a provisional arrangement led by the Ministry of Justice and the Executive Secretariat at Anvisa.[18] Later, in 2003, the enactment of Law 10,742/2003, established the "regulations for the pharmaceutical sector, to promote pharmaceutical services to the population, through mechanisms that stimulate availability and competitiveness in the pharmaceutical sector". It extinguished CAMED and created the Drug Market Regulation Chamber (CMED).[19]

CMED has an intersectoral governance mechanism with a Ministerial Council, with the Minister, chief of staff of the Presidency of the Republic (Casa Civil), Ministers of Health (chair), Economy and Justice and Public Safety, an Executive Technical Committee, with Secretaries from the ministries and the Executive Secretariat at Anvisa.[19–21] CMED has kept its configuration today, except that the Ministry of Industry and Commerce (MDIC) was merged with the Ministry of Economy in 2019.[22]

The Drug Market Regulation Chamber Executive Secretariat (SCMED) at Anvisa is responsible for implementing the decisions and following the guidelines given by the Ministers and the Executive Technical Committee (CTE), including the primary review and price decisions, referred hereafter as "pricing", regulation of commercialisation margins, the definition of annual price adjustment index, public procurement discounts, market monitoring, supporting the decision making, coordinating technical groups, enforce the regulations by investigating and applying the correspondent penalties, among other activities.[19,23]

In 2003, the Secretariat of Science, Technology, and Strategic Inputs (SCTIE) was established as part of a reform of the MoH. It became the champion of the medicines policy implementation, alongside the policy of health science and technology and management of health technologies in the SUS. SCTIE holds the stewardship for the pharmaceutical policy implementation, alongside the policies of health science and technology, and management of health technologies at SUS, among others.[24–28] These last two policies were formulated taking into account the health industrial complex, where the SUS as an oligopsony, stimulates research, development, production of medicines and other technologies to address the health needs and fill the gaps.[29]

In 2006, the MoH established the Technology Incorporation Committee (Citec), responsible for advising the Minister of Health about coverage of medicines at the SUS. The Law 12,401/2011 extinguished Citec and established the National Committee for Health Technology Incorporation at SUS (Conitec) and the mechanisms to support decision-making, taking into consideration economic evaluation, and budgetary impact, contributing to ensuring access to these technologies in the SUS, making the use of Health Technology Assessment (HTA) mandatory. The decree 7,646/2011 details Conitec's composition, functions and procedures.[30,31]

All technologies require marketing authorisation and medicines also require maximum approved prices by CMED before Conitec's appraisal, which can be requested by anyone. The status of the appraisals, information about the composition, agenda and recorded meetings of the committee, recommendations (both positive and negative decisions), regulations, clinical protocols and therapeutic guidelines are available at the MoH's portal.[28,30]

Supplementary Figure S3. Review of the Pricing Regulation – Resolution CMED 02/2004 and prospects of a National Health Technology Assessment Agency

The Drug Market Regulation Chamber (CMED) Resolution 02/2004 establishes the criteria for defining the prices of new products and new pharmaceutical presentations referred to in Article 7 of Law no. 10,742/2003. There were several supplementary regulations and attempts of revision. The Executive Secretariat of Drug Market Regulation Chamber (SCMED) announced the development of the Regulatory Impact Analysis (RIA) for reviewing the pricing regulation of the Resolução CMED 02/2204 in 2019.[32] The RIA is a legal requirement for the development or amendment of regulations in Brazil.[32–37]

At the time of writing of this manuscript, no results of the RIA were made public, despite the public consultation 02/2021, approved by the CTE and published by the Ministry of Economy, lacking the RIA supporting its review.[38] Among the proposed changes, there is a bonus price for the so-called "incremental innovation" medicines, up to 35% over the price of the innovative medicine and a proposal to establish the price for non-innovative biologicals up to 85% of the comparator.[38]

The proposal has been heavily criticised by the pharmaceutical sector and civil society.[39–42] Industry and patient organisations aligned with industry's interest, considered it does not offer enough changes and flexibilities for allowing higher prices for medicines coming into the market with less robust evidence.[43,44] The National Health Council issued a series of recommendations, including the reform of the regulatory committee and requested suspending the public consultation.[45]

At the same time, academics and civil society organisations aligned with the population health perspective call for more transparency and rules that can allow prices to reflect the therapeutic value of the medicines, price adjustments and review during the life cycle of the medicines (to reduce the huge differences between maximum approved prices and actual prices), changing the composition of the basket for external reference prices, with countries with Health Development Index (HDI) similar to Brazil, among other issues.[39–42] Changing the legal provision for price review is a longstanding request from consumer organisations.

A bill is under discussion at the Brazilian Senate (PL 5591/20) that aims to amend the economic regulation of pharmaceuticals, expand the composition of CMED, allowing price review, among other issues.[46] It is necessary to ensure access to medicines and other technologies within the legal and established policies and mechanisms, ensuring a fair price and "value for money".[47–49]

Another proposal on the table is the establishment of a National Agency for Health Technology Assessment to bring together activities currently developed by the National Committee for Health Technology Incorporation at SUS (Conitec), (Permanent Committee for Health Regulation (COSAÚDE) and the Executive Secretariat of the Drug Market Regulation Chamber (SCMED). A study on the topic was commissioned. Even though, the study is supported by extensive bibliographic search and analysis, technical visits to HTA agencies of reference and discussions related to the HTA related to Conitec's work, the proposal lacks the same scientific rigour for research and analysis of evidence for pricing, regarding the structure and the role of SCMED.[50] Therefore, a more in-depth review and analysis of evidence, as well as the dialogue with stakeholders, especially with the society could be beneficial.

According to the Health Organic Law (Law no. 8080/1990 amended by Law no. 12,401 of 2011), the payment or reimbursement as well as dispensing, procurement or importing of medicines, products and experimental clinical or surgical procedure, or with indication not authorised by the Brazilian Health Regulatory Agency (Anvisa) is not allowed.[30,51] The Law 14,313, approved on March 21, 2022, amended the Health Organic Law introducing two exceptions, authorising the incorporation of medicines and other products into the SUS with an indication different from that approved by Anvisa, provided that their use had been recommended by Conitec, with demonstrated scientific evidence on efficacy, accuracy, effectiveness and safety, and its use standardised in a protocol established by the Ministry of Health and also for drugs

and other products to be procured through international multilateral organisations, to be used in public health programmes of the Ministry of Health and its related entities".[52] Some consider these changes can undermine the existing policies, while others consider that it would have very little impact on the SUS and can even have positive outcomes if there is a public health need with robust evidence but for commercial reasons not authorised in Brazil.[53]

These are few examples of the vital importance of strengthening the technical capacity of the pricing and reimbursement bodies, independently of their institutional arrangements and that corporate social responsibility, marketing authorisation, pricing and reimbursement policies need to be considered in a broader, social context.[54]

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